

**REMARKS/ARGUMENTS**

Claims 1-32 are pending and stand substantively rejected. Claims 33-40 were previously withdrawn. In this Amendment, claims 12 and 32 are amended, and new claims 41 and 42 are added. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Office Action.

Support for the amendment to claim 12 can be found in the originally filed disclosure at, for example, figure 3. Support for the amendment to claim 32 can be found in the originally filed disclosure at, for example, figures 5 and 6. Support for new claims 41 and 42 can be found in the specification at, for example, paragraph [0014]. No new matter is introduced.

First Rejection Under 35 U.S.C. §103

¶13. Claims 1, 4, and 12-15 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 5,368,557 to Nita et al. ["Nita '557"] in view of U.S. Patent No. 6,450,975 to Brennan et al. ["Brennan"]. This rejection is traversed.

According to MPEP 2143, a *prima facie* case of obviousness requires, among other things, that the references when combined must teach or suggest all the claim elements. The proposed combination of Nita '557 and Brennan has not been shown to meet this test.

Currently Pending Independent Claim 1

Presently pending claim 1 is drawn to an ultrasound catheter that includes, among other things, a guidewire tube that contacts the ultrasound member. The Office Action alleges this feature is inevitably shown in Nita '557 given the size of the device and the means by which it will be used in a patient's vasculature. Applicants disagree.

The doctrine of inherency is discussed in MPEP § 2112 (IV), which says the fact that a certain result or characteristic *may* occur or be present in the reference is not sufficient to establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference. The salient question then is not whether the presently claimed contact between the guidewire tube and the ultrasound member *may* be present in Nita '557, but rather whether the undisclosed element *must* flow as a natural consequence from the technological

constraints of Nita '557. Applicants submit that Fig. 3 of Nita '557 does not show that the presently claimed contact *must* occur.

As noted at col. 4, lines 16-26, Nita '557 facilitates direct transmission of the quanta of ultrasonic energy passing through the individual ultrasound transmission members 28a, 28b and 28c to the distal head member 30. In comparison, the presently claimed ultrasound catheter involves a guidewire tube that contacts the ultrasound member, and thus a portion of the quanta of ultrasonic energy passing through ultrasound transmission member can be diverted to the guidewire tube. Such diversion can facilitate a guidewire movement within the guidewire tube. Moreover, Fig. 5 of U.S. Patent No. 5,324,255 to Passafaro et al. (cited elsewhere herein) depicts a guidewire tube 90 having an aperture 92 through which an ultrasound transmission member 28 passes. As noted in Passafaro at col. 8, lines 52-56, the ultrasound transmission member 28 passes through the aperture 92 "*without damping or interference from*" the body of the diverter tube 90. Thus, it should not be assumed that contact between a guidewire tube and an ultrasound transmission member is inevitable, based on the rationale that the size of the device and the means by which it will be used in a patient's vasculature. As indicated by Passafaro, such contact is neither inevitable nor inherent. Withdrawal of this rejection with respect to claim 1, and to claim 4 which depends from claim 1, is respectfully requested.

Currently Pending Independent Claim 12

Amended independent claim 12 is drawn to an ultrasound catheter for disrupting occlusions in blood vessels. The catheter includes, among other things, an elongate flexible catheter body having, a distally narrowing taper, an ultrasound transmission member extending longitudinally through the lumen of the catheter body and having a distally narrowing taper, wherein the distally narrowing taper of the ultrasound transmission member extends distally beyond the distally narrowing taper of the elongate flexible catheter body. This combination of elements has not been shown in Nita '557 and Brennan. Withdrawal of this rejection with respect to claim 12, and to claims 13-15 which depends from claim 12, is respectfully requested.

Second Rejection Under 35 U.S.C. §103

¶14. Claims 2 and 3 were rejected under 35 U.S.C. §103(a) as allegedly obvious over the combination of Nita '557 and Brennan, and further in view of U.S. Patent No. 6,544,215 to Bencini et al. ["Bencini"]. This rejection is traversed.

As noted above, the combination of Nita '577 and Brennan has not been shown to teach or suggest an ultrasound catheter that includes, among other things, a guidewire tube that contacts the ultrasound member. Bencini discusses a steerable device for introducing an apparatus into the body, but has not been shown to teach or suggest a guidewire tube that contacts an ultrasound member. As discussed above with regard to independent claim 1, the proposed combination of Nita '557 and Brennan has not been shown to teach or suggest this feature as well. Withdrawal of this rejection is respectfully requested.

Third Rejection Under 35 U.S.C. §103

¶15. Claim 6 was rejected under 35 U.S.C. §103(a) as allegedly obvious over the combination of Nita '557 and Brennan, and further in view of U.S. Patent No. 6,616,617 to Ferrera et al. ["Ferrera"]. This rejection is traversed.

Ferrera discusses a vasoocclusive device for the treatment of aneurysms, but has not been shown to teach or suggest a guidewire tube that contacts an ultrasound member. As discussed above with regard to independent claim 1, the proposed combination of Nita '557 and Brennan has not been shown to teach or suggest this feature as well. Withdrawal of this rejection is respectfully requested.

Fourth Rejection Under 35 U.S.C. §103

¶16. Claims 5 and 7 were rejected under 35 U.S.C. §103(a) as allegedly obvious over the combination of Nita '557, Brennan, and Bencini, and further as a matter of design choice. This rejection is traversed.

As discussed above with regard to independent claim 1, the proposed combination of Nita '557 and Brennan has not been shown to teach or suggest a guidewire tube that contacts an ultrasound member. The proposed design choice does not address this feature. Withdrawal of this rejection is respectfully requested.

Fifth Rejection Under 35 U.S.C. §103

¶17. Claims 16-19 were rejected under 35 U.S.C. §103(a) as allegedly obvious over the combination of Nita '557 and Brennan, and further in view of U.S. Patent No. 6,179,809 to Khairkhahan et al. ["Khairkhahan "]. This rejection is traversed.

According to MPEP 2143, a *prima facie* case of obviousness requires, among other things, that there must be some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to the artisan, to combine the references. Moreover, the proposed combination must teach or suggest all of the claim elements. The proposed combination of references does not meet these tests.

Presently pending independent claim 16 is drawn to an ultrasound catheter for disrupting occlusions in blood vessels. The catheter includes, among other things, an elongate flexible catheter body, an ultrasound transmission member extending longitudinally through the lumen of the catheter body. The ultrasound transmission member conforms to at least one bend in the distal portion of the catheter body.

The Office Action alleges that the combination of Nita '557 and Brennan does not provide a catheter body having a bend, but that Khairkhahan provides a catheter with a bend. Applicants submit that it would not have been obvious to modify the combination of Nita '557 and Brennan with the catheter of Khairkhahan, for at least the following reasons.

Nita '557 and Brennan both involve ablative ultrasound devices. In contrast, Khairkhahan discusses a drug delivery device which may include an imaging ultrasound transducer. There are often structural differences between *ablative* and *imaging* catheters. Referring to the instant application at paragraph [0004], an ablative ultrasonic catheter typically involves a transducer that creates vibrational energy. The vibrational energy is transmitted from the transducer through the ultrasound catheter via an ultrasound transmission member running longitudinally through the catheter. The transmission member transmits the vibrational energy to the distal end of the catheter where the energy can be used for ablation.

Khairkhahan's catheter is a very different type of apparatus. Khairkhahan discusses an annular ultrasound transducer that can be placed distally on the distal tip of a catheter (col. 11, lines 54-57). The distally located transducer transmits and receives imaging

signals. Hence, the general scope of Khairkhahan is outside the pertinent field of endeavor of the presently claimed invention, and is not a proper §103 reference according to MPEP 2141.01(a) because it is a non-analogous reference. Moreover, due to the fundamental structural differences between Nita '577 and Brennan as compared with Khairkhahan, the artisan would not be motivated to combine these references.

Moreover, there is no hint or suggestion in Khairkhahan of an ultrasound transmission member. Relatedly, there is no discussion in Khairkhahan that the ultrasonic imaging transducer conforms to the bend in the catheter. Thus, assuming for the sake of argument only that Khairkhahan *could* be combined with Nita '557 and Brennan, the combination would not provide an ultrasound transmission member that conforms to at least one bend in a distal portion of a catheter body as presently claimed. Based on the above, Applicants submit that a *prima facie* case of obviousness has not been established. Withdrawal of this rejection with respect to claim 16, and to dependent claims 17-19, is respectfully requested.

Sixth Rejection Under 35 U.S.C. §103

¶18. Claims 20-25 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 5,324,255 to Passafaro et al. [“Passafaro”] in view of Brennan. This rejection is traversed.

According to MPEP 2143, a *prima facie* case of obviousness requires, among other things, that the references when combined must teach or suggest all the claim elements.

Presently pending claim 20 is drawn to an ultrasound catheter that includes, among other things, an elongate flexible catheter body having lumen, a guidewire tube disposed within the lumen, and an ultrasound transmission member. The guidewire tube includes at least one opening within the catheter body for providing contact between a guidewire extending through the guidewire tube and the ultrasound transmission member. The ultrasound transmission member passes through the guidewire tube via the at least one opening to contact the guidewire.

Passafaro discusses an ablative device having onboard ultrasound components. According to the Office Action, Fig. 5 of Passafaro discloses contact between an ultrasound transmission member and a guidewire. The Office Action provides additional analysis at page 4,

paragraph 12, stating it is inevitable that given the size of the device and the means by which it will be used that the transmission member and the guidewire will contact each other. Applicants disagree. Although Fig. 5 depicts an ultrasound transmission member in proximity with a guidewire, it has not been shown that Passafaro clearly discloses contact between an ultrasound transmission member and a guidewire as presently claimed. As noted above, according to Passafaro at col. 8, lines 52-56, the ultrasound transmission member 28 passes through the aperture 92 “*without damping or interference from*” the body of the diverter tube 90. Thus, there is no contact between the guidewire tube and the ultrasound member, and for at least the same reason it should not be assumed that contact between a guidewire and an ultrasound transmission member is inevitable, based on the rationale that the size of the device and the means by which it will be used in a patient's vasculature. As suggested by Passafaro, such contact is neither inevitable nor inherent. Withdrawal of this rejection with respect to claim 20, and to dependent claims 21-25, is respectfully requested.

Seventh Rejection Under 35 U.S.C. §103

¶19. Claim 32 was rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 5,312,328 to Nita et al. [“Nita ‘328”] in view of Brennan. This rejection is traversed.

According to MPEP 2143, a *prima facie* case of obviousness requires, among other things, that the references when combined must teach or suggest all the claim elements.

Amended independent claim 32 is drawn to an ultrasound catheter that includes, among other things, an elongate flexible catheter body, an ultrasound transmission member, and a guidewire tube. The guidewire tube has a longitudinal axis that is different from a longitudinal axis of the catheter body. The patentability of axis alignments are discussed further below in the following section. The combination of Nita ‘328 and Brennan has not been shown to discuss this combination of elements. Withdrawal of this rejection is respectfully requested.

Eighth Rejection Under 35 U.S.C. §103

¶20. Claims 26-30 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Nita ‘557 in view of Brennan, and further as a matter of design choice. In a telephone

communication of April 25, 2007, the Examiner indicated that claim 8 is also included in this rejection. This rejection is traversed.

Presently pending independent claim 26 is drawn to an ultrasound catheter that includes, among other things, an elongate flexible catheter body, an ultrasound transmission member, and a distal head having a guidewire lumen with a different longitudinal axis than a longitudinal axis of the catheter body.

The Office Action alleges that a guidewire lumen with a different longitudinal axis than a longitudinal axis of the catheter serves no particular purpose, and thus should not be considered when determining patentability of the claim. Applicants disagree. Such configurations can allow an ultrasound transmission member and a guidewire tube to fit within a catheter body having a smaller inner diameter, as indicated in the instant specification at paragraph [0047]. The Office Action also states that a non-parallel guidewire lumen is capable of facilitating tracking equally as well as the present application. It is not clear how or why this conclusion is relevant for the purposes of patentability. If this rejection is maintained, Applicants request that the regulatory or statutory basis for this rule be provided.

Withdrawal of this rejection with respect to claim 26, and to dependent claims 27-30, is respectfully requested. Presently pending independent claim 8 is drawn to an ultrasound catheter that includes a distal head having a guidewire tube portion with a longitudinal axis that is not parallel to an overall longitudinal axis of the catheter body. For many of the reasons stated above with regard to claim 26, Applicants submit that claim 8 is also nonobvious. Withdrawal of this rejection is respectfully requested.

Ninth Rejection Under 35 U.S.C. §103

¶21. Claim 9 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Nita '557 in view of Brennan, and further as a matter of design choice as applied to claim 8 above, and further in view of Bencini. This rejection is traversed.

Presently pending independent claim 8, from which claim 9 depends, is drawn to an ultrasound catheter that includes a distal head having a guidewire tube portion with a longitudinal axis that is not parallel to an overall longitudinal axis of the catheter body. As

indicated in the previous section, this combination of elements has not been shown in Nita '557 and Brennan. Withdrawal of this rejection is respectfully requested.

Tenth Rejection Under 35 U.S.C. §103

¶22. Claims 10 and 11 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Nita '557 in view of Brennan, and further as a matter of design choice, and further in view of Ferrera as a matter of design choice.

Presently pending independent claim 8, from which claims 10 and 11 depend, is drawn to an ultrasound catheter that includes a distal head having a guidewire tube portion with a longitudinal axis that is not parallel to an overall longitudinal axis of the catheter body. As indicated above, this combination of elements has not been shown in Nita '557 and Brennan. Withdrawal of this rejection is respectfully requested.

Eleventh Rejection Under 35 U.S.C. §103

¶23. Claim 31 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Nita '557 in view of Brennan, and further as a matter of design choice, and further in view of Nita '328.

Presently pending claim 31 depends from independent claim 26. As discussed above, Nita '557 and Brennan have not been shown to teach or suggest a distal head having a guidewire lumen with a different longitudinal axis than a longitudinal axis of the catheter body as described in claim 26. Moreover, Nita '328 has not been shown to teach or suggest this claim feature. Hence, presently pending claim 31, which depends from claim 26, is nonobvious. Withdrawal of this rejection is respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.



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